



The Search for a “Better Way:” The Evolution Leading to the SMRB

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National Institutes of Health



The 65-Year Mission of NIH

Section 301 of the PHS Act – “The Secretary shall conduct in the Service and encourage, cooperate with, and render assistance to other appropriate public authorities, scientific institutions, and scientists in the conduct of, and promote the coordination of, research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man”

The NIH is the primary Federal agency for conducting and supporting medical research



Key Moments in Legislative History

- March 3, 1879 – National Board of Health to lead first Federal medical research effort
- March 3, 1901 – Hygienic Laboratory to investigate matters pertaining to public health
- August 14, 1912 – Public Health Service created to research “diseases of man.”
- August 5, 1937 – NCI created
- July 1, 1944 – Passage of Public Health Service Act, creates first National Institutes of Health
- June 10, 1993 – NIH Revitalization Act passed
- January 15, 2007 – NIH Reform Act Signed

Evolution of NIH Reauthorization

- 1944 - 1985 – Individual bills amending missions of existing ICs or creating new ICs.
- 1985 – First omnibus reauthorization of NIH.
- 1993 – Second omnibus reauthorization of NIH.
- 1993 – 2004 – Authorization process subsumed by appropriations laws. Some individual bills created new ICs or amended authorities. Failed attempt for omnibus reauthorization in 1996.
- 2004 –2006– Post doubling era, focus on accountability and oversight, passage of NIH Reform Act.
- Today – NIH emerges into new era of hope and vitality. ARRA and FY 2009 budget increase signal upward funding trend.

Public Health Service Act

Key Authorities for NIH

- Prioritizes Research Through Organizational Structure
- Authorizes Biomedical Research
- Provides Grantmaking Authority
- Authorizes Peer Review
- Authorizes Training
- Authorizes Dissemination of Information
- Requires Human Subjects Protections
- Authorizes the Solicitation of Public Advice

External Political Factors Driving Growth and Organizational Design of NIH

- World War II
- Academic Medical Centers
- Advances in Methods of Discovery
- Patient Advocates

Science, The Endless Frontier

- “With particular reference to the war of science against disease, what can be done now to organize a program for continuing in the future the work which has been done in medicine and related sciences?”

Question from President Roosevelt to Vannevar Bush, Director, Office of Scientific Research and Development, July 25, 1945

Establishing the NIH Model

- “The responsibility for basic research in medicine and the underlying sciences, so essential to progress in the war against disease, falls primarily upon the medical schools and universities...the Government should extend financial support to basic medical research in the medical schools and universities.”
- Vannevar Bush’s Response to FDR in Science, the Endless Frontier.



Success and Fear Spurs Growth

- Advances in Basic Research, from discovery of design of DNA to Sequencing of Human Genome.
- Remarkable increases in life expectancy.
- The toll of cancer, the shock of the AIDS epidemic, the ability to diagnose and respond.
- Bioterrorism and the threat of global diseases.

Political Lobbying

- Scientists largely apathetic, not a major political force.
- Academic Health Centers and Universities motivated and effective.
- Patient and disease advocates, organized, potent and results oriented – perfected lobbying techniques, spurred the doubling and expansion of Institutes and Centers.

Examples of Congressional Actions Since 1993

- Creation of new offices, Institutes or Centers – NCCAM, NCMHD, NIBIB, Nursing Institute, ORWH, OBSSR, Office of Rare Diseases.
- New programs – IDeA, Parkinson's disease centers, Pediatric Research Initiative, Pain Consortium, Autism Centers and Interagency Autism Committee, Loan Repayment, Muscular Dystrophy Centers.

1993-2003 Appropriations Laws Dominate NIH's Legislative Arena

- 1993 - \$10.3 billion
- 2003 - \$27.2 billion

Key Period of Doubling

- 1998 - \$13.6 billion
- 2003 - \$27.2 billion
- Flat Funding 2004-2008

2004

Shift From Appropriations Emphasis To Authorization Process

National Institutes of Health Reform Act of 2006 (P.L. 109-482)

- Passed Congress with virtually unanimous support (Dec 2006)
- Signed into law by the President (Jan 2007)
- Key Features of Act:
 - ♦ Institutional mechanism for supporting trans-NIH research
 - ♦ Transparent disease reporting
 - ♦ Shift from political review to SMRB

One Hundred Ninth Congress
of the
United States of America

AT THE SECOND SESSION

*Began and held at the City of Washington on Tuesday,
the third day of January, two thousand and six*

An Act

To amend title IV of the Public Health Service Act to revise and extend the authorities of the National Institutes of Health, and for other purposes.

*Be it enacted by the Senate and House of Representatives of
the United States of America in Congress assembled,*

SECTION 1. SHORT TITLE.

This Act may be cited as the “National Institutes of Health Reform Act of 2006”.

TITLE I—NIH REFORM

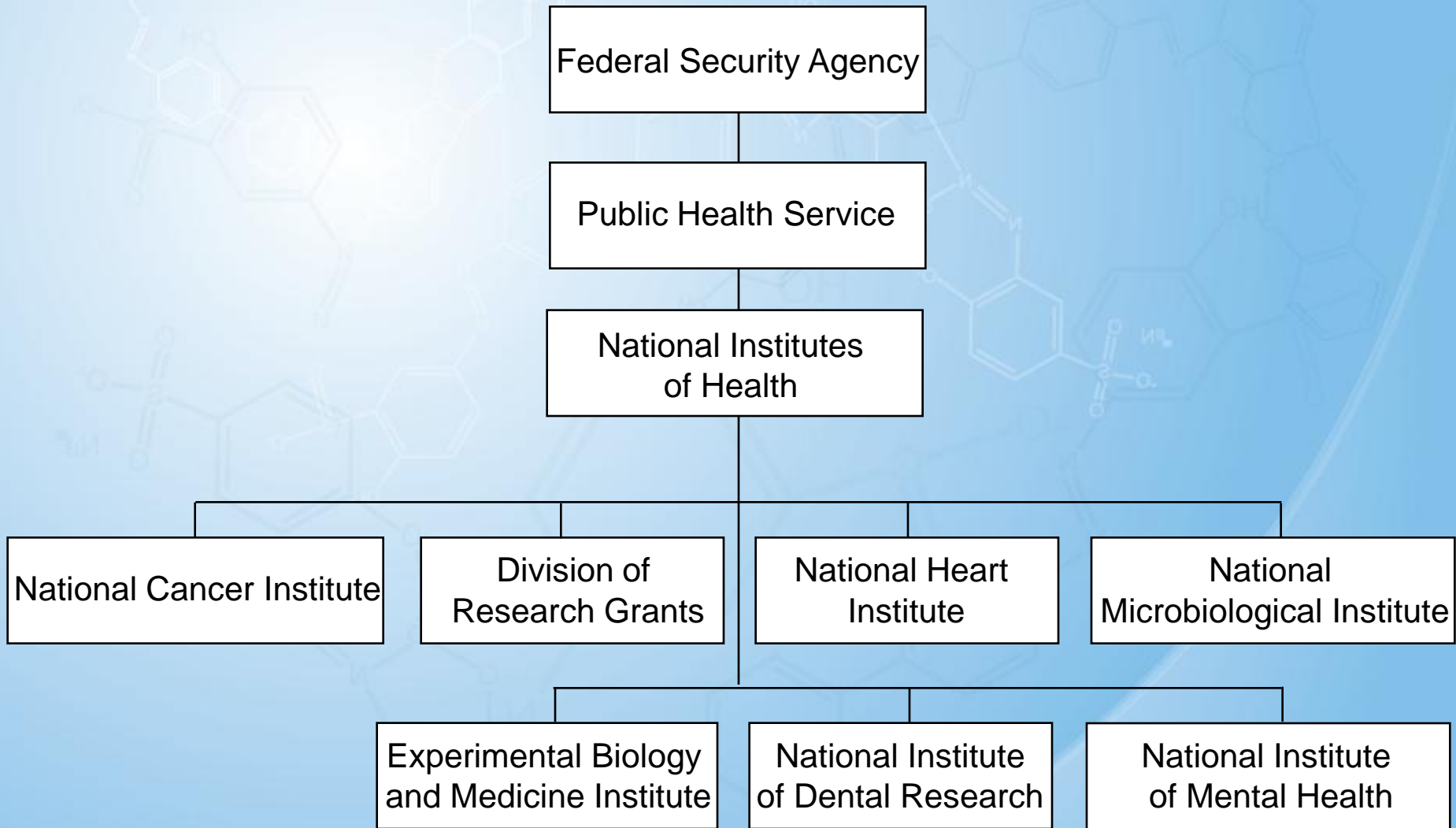
Organizational Evolution of the NIH: 1937

Public Health Service

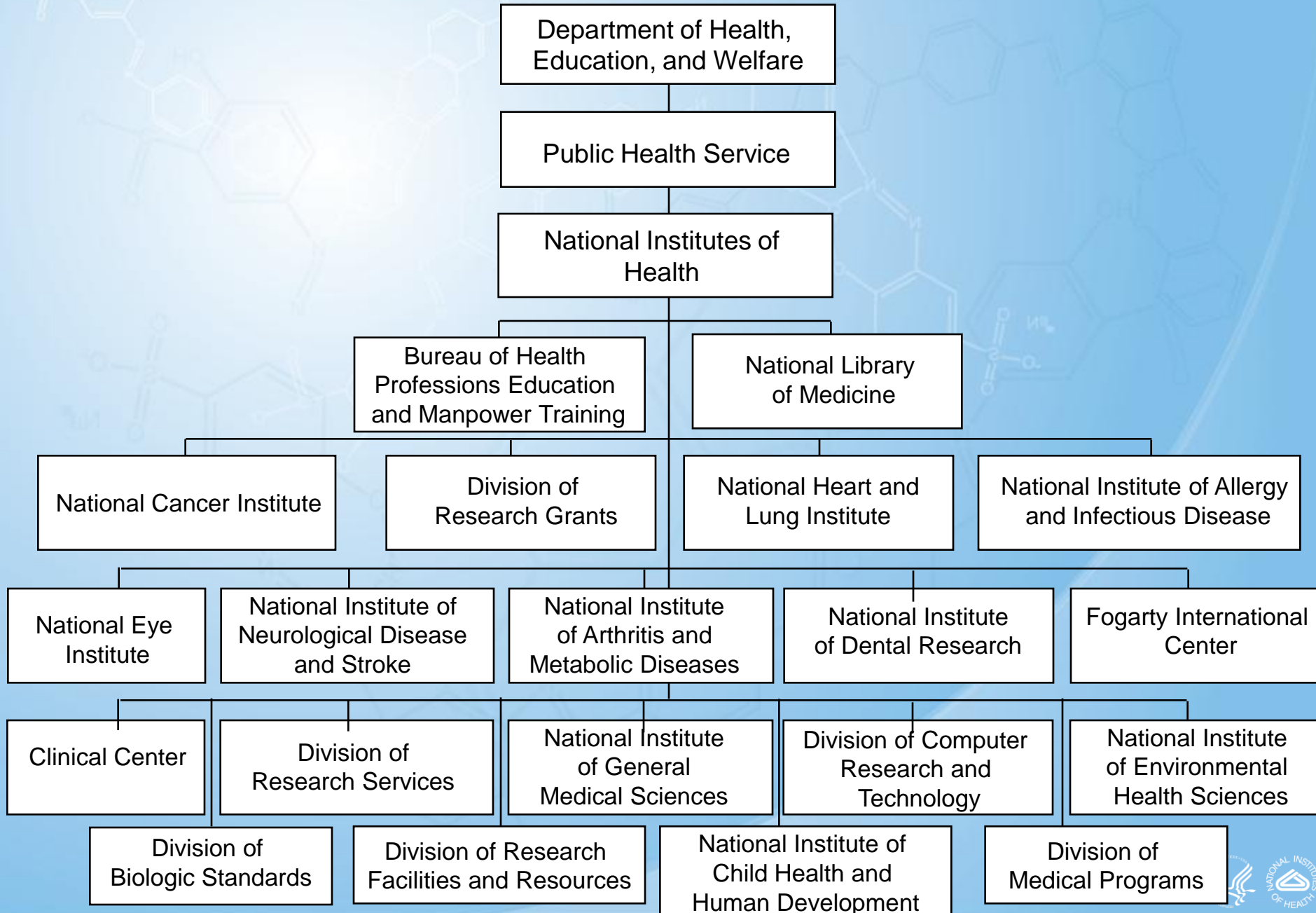
National Institute
of Health

National Cancer Institute

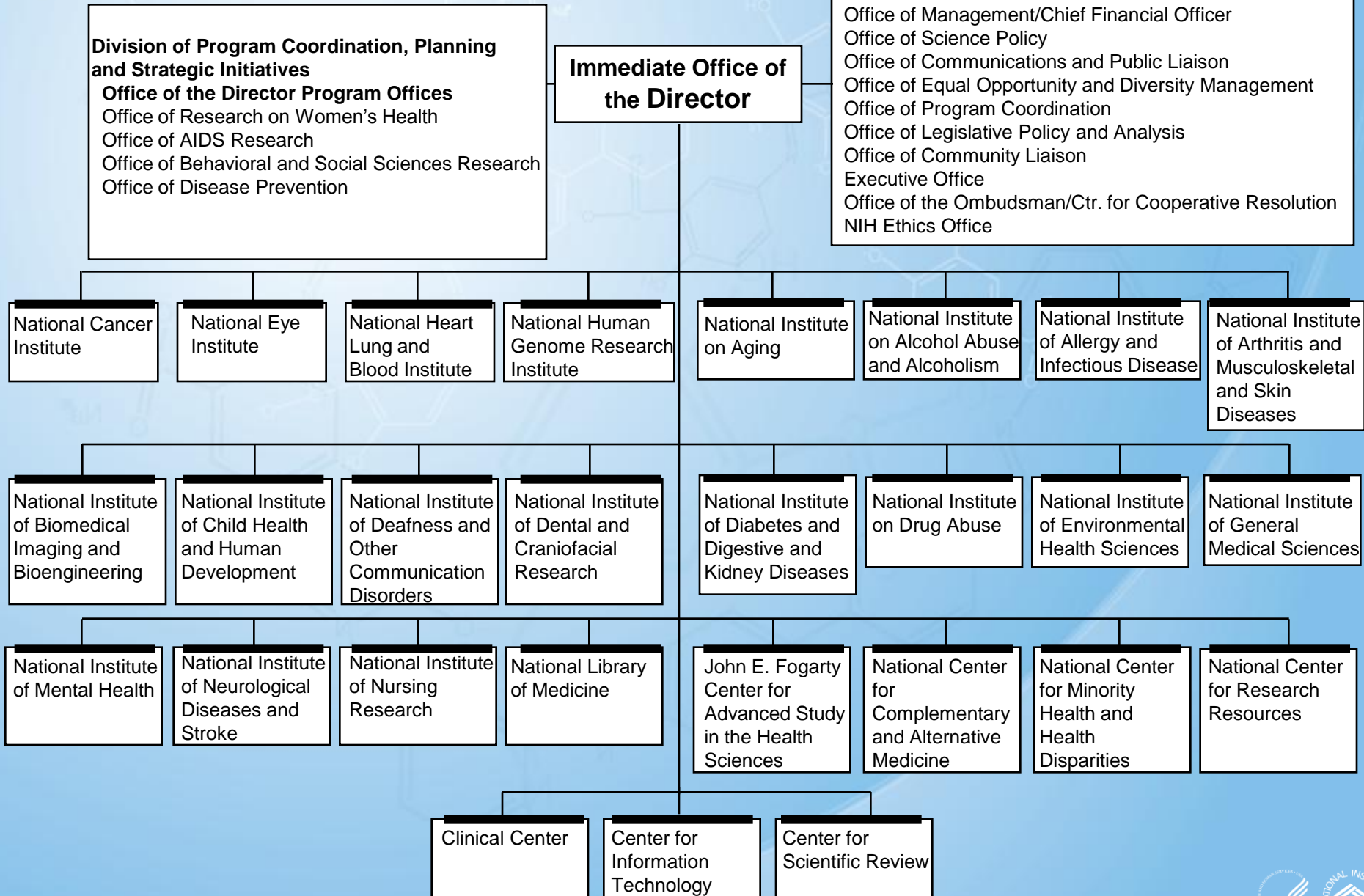
Evolution of the NIH: 1947 - 1949



Evolution of the NIH: 1969



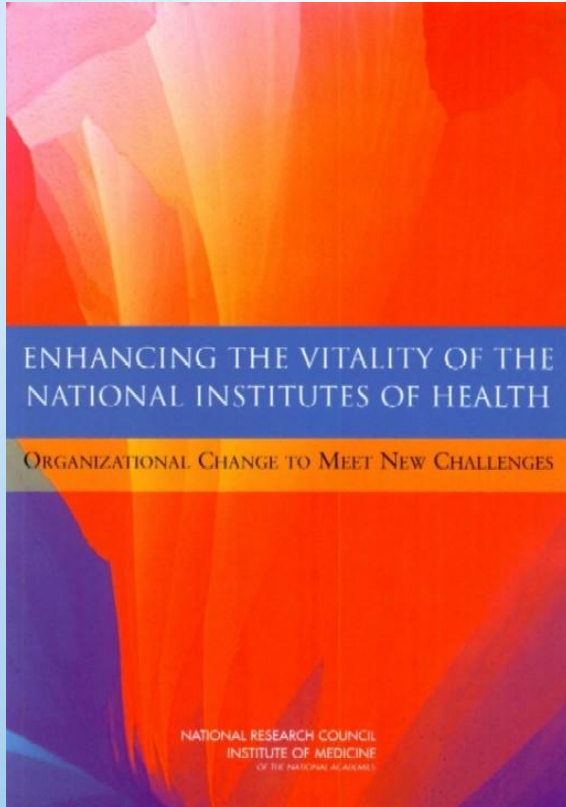
NIH Today



“While the NIH is to be celebrated, success alone does not answer fully the question of whether there is a better way to proceed, particularly as one faces a future where the world of biomedical science is being rapidly transformed in virtually all its dimensions.”

Institute of Medicine

Enhancing the Vitality of the National Institutes of Health: Organizational Change to Meet New Challenges (2003)



Excerpts from Chairman Barton's Hearing Statement – March 17, 2005

- ***Unfortunately, NIH has grown like Topsy. In 1960, NIH was comprised of a director and seven institutes. Now there are 27 Institutes and Centers. While the motivation behind this explosive growth was certainly sincere, the individual organizations were created arbitrarily, usually without benefit of systemic analysis or review of the efficiency of this structure.***





- ***This growth has resulted in an almost random collection of structures in which largely independent institutes and centers are tasked to advance research programs not in cooperation with one another, but according to diseases, organ systems, or stage of life in which they specialize. Thus we study diabetes and aging in separate places, with separate staffs and separate directors overseeing the research. Plainly there is collegiality and professional cooperation, but it defies reason to believe they will produce the efficiencies that can be achieved by logically unified structure.***



- *Furthermore, this “silo” system produces thousands of pages of strategic plans, one for each of the 27 Institutes and Centers comprising the NIH. Read separately, each Institute and Center produces an impressive list of research goals and targets. Realistically, **scientific progress can not be accurately measured and strategic plans set by evaluating the research activities of one Institute alone when modern science transcends the research activities at several Institutes and Centers.***

Dr. Harold Varmus

- Many people with influence in Washington view the National Institutes of Health as 'the jewel in the crown of the federal government.' Such praise has helped to enhance the value--the number of carats--in this jewel, especially over the past few years. But considerably less attention has been given to its shape than its price. **New facets are being added without much thought to overall design, providing a superficial sparkle that may be pleasing to the few, but threatening to the functional integrity of the entire gem.** With too many surfaces of different sizes, the organization may soon become less able to take advantage of its extraordinary budget increase and more difficult to manage responsibly. **Those who care about the NIH need to think about its form and propose some solutions before the structure becomes even more fragmented and harder to fix.**



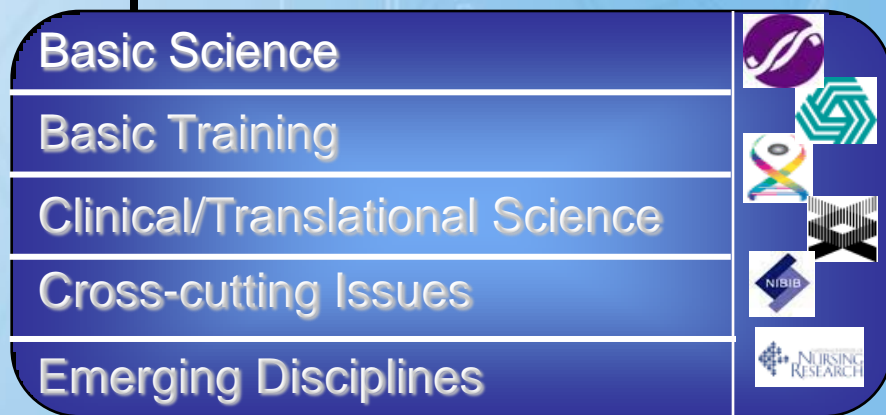
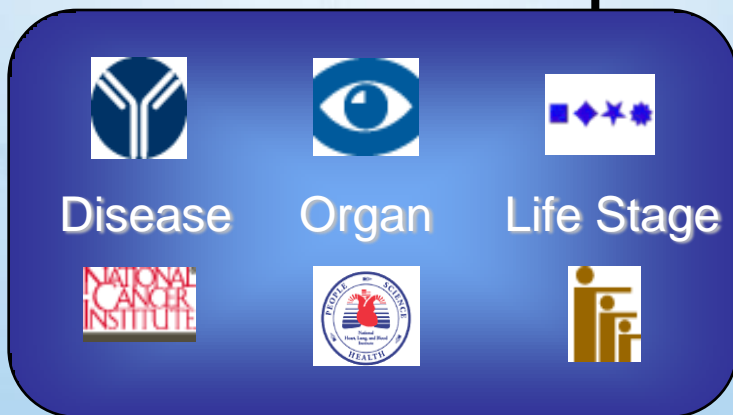
Dr. Elias Zerhouni

- Over the years the NIH has had what I call a structural approach to portfolio management. **Anytime there was a need and a vocal constituency, and Congress agrees, a structure was added to the NIH. That structure would get an appropriation that would grow in lockstep with all of the other structures.** The problem here is that no one cares for the entire institution except the director . . . at the end of the day we need a new way to manage the portfolio, and that's what I call functional portfolio management. The director needs the ability to merge the fourteen different tracking systems that have developed to record and code what the NIH does . . . We need to be able to plan across NIH. We need some funds in common. **If you have twenty-seven fingers out there with no palm, you don't have a hand.**



Congressional Conceptual Framework for NIH

OD
Deputy and Associate Directors
Administrative Offices



OD Division of Program Coordination, Planning, and Strategic Initiatives

Includes the 5 Specific Program Coordination Offices
Which Will Continue Their Roles

The Intent for the SMRB

- “In response to the IOM suggestion that there is need for public process when considering proposed changes in the number of NIH institutes and centers, the National Institutes of Health Reform Act of 2006 creates a formal, public process to review the structural organizational design of the agency every seven years. A ‘scientific management review’ group comprised of institute and center directors and other scientific experts would evaluate the structural design of the existing institutes and centers at the NIH, and proposed new institutes, and recommend necessary restructuring plans.” **House Report 109-687**



NIH

Ideas

People

Resources

Leadership

